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Section 5 - 510(k) Summary

Technological characteristics:	The proposed device has the same technological characteristics as the predicate device(s) with difference being the use of 5-FU to prevent bacterial colonization.
Performance tests:	The product meets all the requirements of ISO 10555-1 (Sterile, single use intravascular catheters) and ISO10555-3 (Sterile, central venous catheters) The following were performed to demonstrate substantial equivalence • catheter stiffness • catheter elongation • catheter flexural fatigue tolerance • priming volume: distal lumen • priming volume: medial lumen • priming volume: proximal lumen • distal lumen flow rate • medial lumen flow rate • proximal lumen flow rate • clinical evaluation
Assessment of non-clinical performance data:	The Angiotech CVC has undergone testing to that provides assurance of safety and effectiveness for its intended use. Testing included both *in vitro* and *in vivo* biocompatibility, *in vitro* zone of inhibition, *in vitro* minimal inhibitory concentration, *in vitro* minimal bactericidal concentration, mechanical and physical testing, and drug release testing.
Assessment of clinical performance data:	The Angiotech® CVC was evaluated in a prospective, randomized clinical trial as compared to the predicate device. Angiotech Catheter insertions in adult patients in an ICU setting proved that the Angiotech CVC was effective and non-inferior when compared to the predicate device for prevention of bacterial colonization on catheters. The comparability of the two devices was further supported by the low rate of catheter-related bloodstream infection, which occurred in none of the Angiotech CVC group and two in the predicate device group. The rates of catheter insertion site infections were low and comparable in the two groups. No adverse effects have been associated with the clinical use of Angiotech CVC. The results of the clinical trial support the intended use of the Angiotech CVC.
Conclusion:	The results of non-clinical and clinical testing demonstrate that the device is as safe and effective as the legally marketed predicate device(s).

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Section 5 - 510(k) Summary

In accordance with 212 CFR 807.87, the following 510(k) summary has been prepared per 21 CFR 8107.92

Angiotech CVC 510(k) Summary

Submitter	Angiotech BioCoatings Corp 336 Summit Point Drive Henrietta, NY 14467 USA
Applicant Contact:	Trudy D. Estridge, Ph.D. Director of Regulatory Affairs Angiotech Dulles Gateway Center 13921 Park Center Road, Suite 100 Herndon, VA 20171 USA Voice: 703-796-8927 Fax: 703-673-0061 Email: testridge@angio.com
Date summary prepared:	December 13, 2007
Device trade name:	Angiotech® CVC
Device Common Name:	Central Venous Catheter (CVC)
Device classification:	Catheter, intravascular, therapeutic, short-term less than 30 days. Product Code FOZ, 21 CFR 880.5200, Class II
Legally marketed devices to which the device is substantially equivalent:	ARROWg+ard Blue® Central Venous Catheter K993691 and K900263
Description of the device:	The Angiotech® CVC Multi-lumen Central Venous Catheter with MEDI-COAT™ Antimicrobial Surface is a 7-French, polyurethane triple lumen, 15 or 20-cm catheter with a MEDI-COAT containing 48.8 µg/cm of 5-fluorouracil.
Intended use of the device:	The multiple-lumen catheter permits venous access to the central circulation. The Angiotech antimicrobial surface is intended to help provide protection against bacterial colonization on the catheter surface and it may help reduce catheter-related infections. The catheter is not intended to be used as a treatment for existing infections, nor is it indicated for longer than 30 days use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Trudy D. Estridge, Ph.D.
Director of Regulatory Affairs
Angiotech Pharmaceuticals, Incorporated
Dulles Gateway Center
13921 Park Center Road, Suite 100
Herndon, Virginia 20171

Re: K073520
Trade/Device Name: Angiotech CVC
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: March 28, 2008
Received: March 28, 2008

Dear Dr. Estridge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

510k number if known: K073520

Device Name: Angiotech CVC

Indications for Use:

The multiple-lumen catheter permits venous access to the central circulation. The Angiotech antimicrobial surface is intended to help provide protection against bacterial colonization on the catheter surface and it may help reduce catheter-related infections. The catheter is not intended to be used as a treatment for existing infections, nor is it indicated for longer than 30 days use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ADW

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073520